March 20, 2017

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Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Submitted electronically via www.regulations.gov

Re: Comments of the American Chemistry Council on EPA's Proposed Rule: *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act*, 82 Fed. Reg. 7562 (January 19, 2017); EPA-HQ-OPPT-2016-0654

Dear Docket Clerk:

The American Chemistry Council (ACC)[1] is pleased to submit the attached comments on the Environmental Protection Agency, Office of Pollution Prevention and Toxics Proposed Rule, Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act.

These comments align with our separately filed comments on the proposed rules describing the processes for inventory reset and prioritization for risk evaluation, and for the development of the scopes for risk evaluation of the first 10 chemicals selected from the TSCA work plan. All comments should be considered together.

Please feel free to contact me with any questions at 202-249-6130 or karyn_schmidt@americanchemistry.com.

Sincerely,

Karyn M. Schmidt
Senior Director, Regulatory and Technical Affairs
American Chemistry Council

cc: Jeffery Morris, Director, OPPT
Wendy Cleland-Hamnett, OPPT
Tala Henry, Director, Risk Assessment Division, OPPT
Susanna Blair, Office of Chemical Safety and Pollution Prevention

[1] ACC represents the leading companies engaged in the business of chemistry. More information about ACC is presented in the body of our comments.

American Chemistry Council

Comments on EPA's Proposed Rule for Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act 82 Fed. Reg. 7562 (January 19, 2017)

March 20, 2017

Karyn M. Schmidt
Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 2nd Street, NE
Washington DC 20002
(202) 249-6130
Karyn_Schmidt@americanchemistry.com

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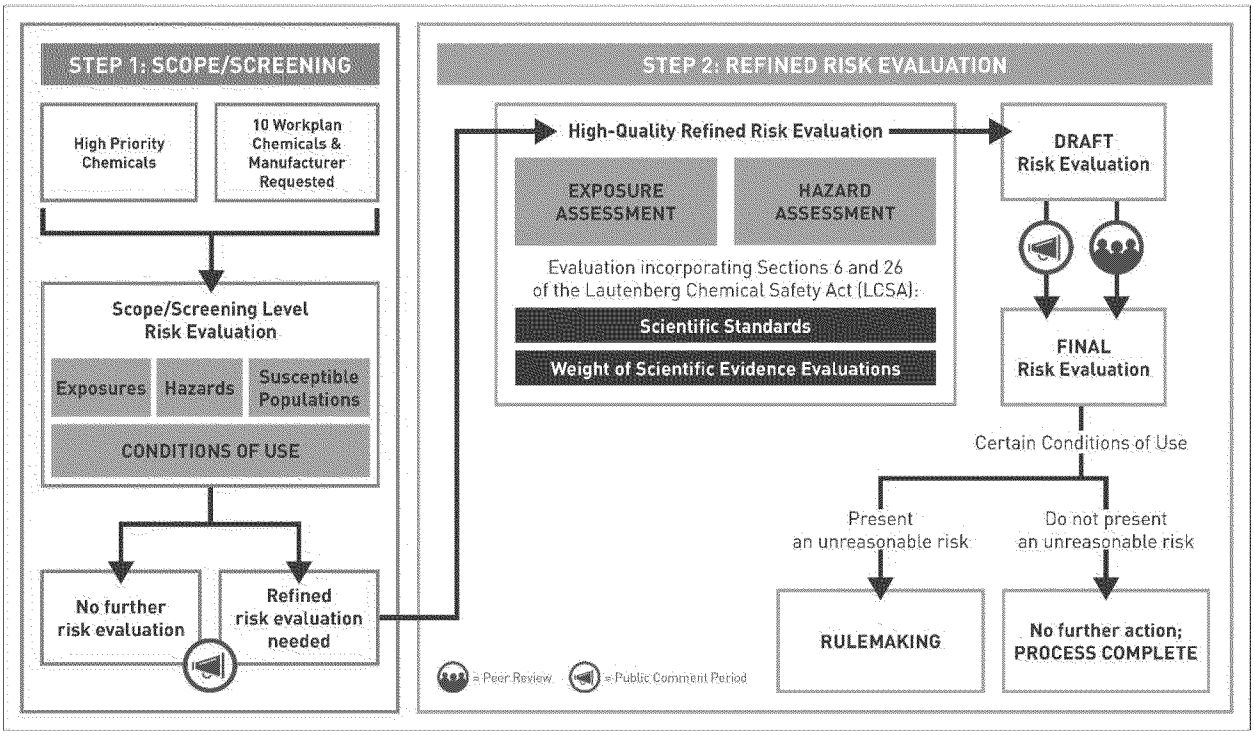
EXECUTIVE SUMMARY

Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), EPA must complete risk evaluations under statutory deadlines and using robust scientific standards. To achieve this goal, EPA must be flexible in its scoping of risk evaluations so it can maintain both pace and quality, and to inform the regulatory decision-making process in the most meaningful way. EPA should conduct its scoping to include conditions of use that are relevant and meaningful to a fit-for-purpose risk evaluation, and well-tailored to the problems and decisions at hand. EPA must incorporate Section 26 science standards throughout the risk evaluation process.

ACC recommends that EPA apply a tiered approach throughout the risk evaluation process. This approach will allow EPA to identify and consider the most relevant and highest risk conditions of use in an efficient and practical manner. The figure below depicts ACC's suggested approach, which is discussed in further detail in Section VI of these comments.



These comments offer overarching comments, specific comments responding to EPA's questions set out in the preamble, and additional specific recommendations for the conduct of risk evaluations under the amended statute. Key observations are:

- EPA must flexibly scope risk evaluations to focus on the most relevant, greatest potential for risk conditions of use.

- EPA should apply a tiered approach throughout risk evaluation, including when identifying and considering relevant conditions of use.

- It is essential that Section 26 science standards are applied to science-based decisions throughout the entire risk evaluation process. These requirements are so central to the function of LSCA risk evaluations that they must be described fully and defined in the regulation so they are applied consistently and stakeholders have adequate notice to participate in the development of the risk evaluations.

- EPA must revise criteria for manufacturer-requested evaluations to align them procedurally with EPA-initiated ones to incentivize their use as contemplated by statute and to make information and certification requests reasonable.

- The rule must ensure that peer reviews strive to provide consensus reports.

- EPA must articulate, with specificity, the scientific approaches and methods it will use in the risk evaluation, rather than simply pointing to Agency guidance which is often outdated, inconsistently interpreted, and inconsistently applied.

- EPA must describe procedures to ensure robust interagency collaborations that include all knowledgeable and potentially affected agencies, and timelines for public comment must be sufficiently robust to allow for a thorough review of EPA analyses.

INTRODUCTION

On behalf of the American Chemistry Council (ACC),[2] we are pleased to submit comments on EPA's proposed procedures for chemical risk evaluation under the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). Risk evaluation is the very heart of LCSA. LCSA envisions a streamlined process whereby all chemicals in commerce are systematically prioritized for, and then subject to, risk evaluation. EPA has described this process as a pipeline. Two critical design elements of LCSA that facilitate movement through the pipeline are the statutorily mandated timelines for risk evaluations and science quality requirements.

Our comments explain why these two design elements of TSCA - the need for timely, high quality risk evaluations – inform the application of a number of key provisions of the amended statute. In short, risk evaluations must be scoped, conducted, and completed in a way that meets statutory deadlines and quality requirements, and these imperatives must govern the way in which EPA applies a number of statutory terms.

Congress intended to redesign how TSCA risk evaluations work, as well as the pace of review. EPA cannot interpret individual provisions and definitions under LCSA to undermine these core objectives.

We offer overarching comments, followed by specific comments responding to EPA's questions set out in the preamble, and conclude with additional specific recommendations on the conduct of risk evaluations.

OVERARCHING COMMENTS

I. EPA Should Flexibly Scope Risk Evaluations to Include those Conditions of Use that Allow Timely Completion of Risk Evaluations and Meet Section 26 Scientific Standards.

Section 6(b)(4)(G) establishes a maximum time period of three years to complete a risk evaluation (subject to a possible extension of six months), with the throughput criterion of having at least 20 risk evaluations on high-priority substances (plus up to 20 risk evaluations of manufacturer-requested chemical substances) underway by December 2019. Congress designed a statute that makes it possible for EPA to meet this throughput requirement by exercising flexibility in scoping risk evaluations, and by selecting the conditions of use targeted for review.

[2] ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

At the same time, risk evaluations must meet Section 26 quality requirements, using best available science and weight of the evidence review.

To achieve the throughput and quality requirements for risk evaluation, Congress designed a process to allow chemicals to be systematically prioritized and evaluated. This design is apparent throughout LCSA. It begins with a reset of the TSCA Inventory -- the full catalog of chemicals in commerce. LCSA requires that the TSCA Inventory be sorted, so that chemicals that are currently active in commerce are separated from those not currently used. This sorting enables EPA to identify only those chemicals that are active in commerce for prioritization and risk evaluation. This statutory design makes eminent sense: it allows EPA to focus resources for its multi-year, time- and resource-intensive risk evaluations on chemicals that are actually being used. From this initial focusing step, LCSA repeatedly requires EPA to further refine its focus throughout prioritization and risk evaluation. EPA must next implement a prioritization process, which further refines the active chemicals in commerce to those that are high priority for risk evaluation. These chemicals must then undergo a scoping exercise to further focus on the conditions of use that will be the subject of the risk evaluation.

In implementing LCSA, EPA has indicated that it intends to identify and consider all conditions of use of a chemical in all risk evaluations, all the time. This interpretation cannot be reconciled with EPA's statutory directive to achieve throughput and quality in risk evaluations. It is inconsistent with the design of the statute; inconsistent with congressional intent to give EPA the flexibility to make case-by-case scoping decisions; and undermines statutory purposes and the effective function of the statute itself.

A. There is No Statutory Mandate to Include All Conditions of Use in the Scope of Every Risk Evaluation Under TSCA § 6(b).

EPA notes in the preamble that, prior to enactment of LCSA, the Agency was "free to and did" conduct risk assessments on selected uses of chemical substances, but that it now interprets the amended statute as "requiring that risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities… [t]hat is to say, a risk evaluation must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance" [emphasis added].[3] ACC strongly disagrees with this interpretation -- EPA is reading a mandate into the statute where none exists. Rather, Congress equipped EPA with the tools to scope risk evaluations in order to achieve statutory purposes, and EPA should use those tools accordingly.

The statute does not require EPA to include "all" conditions of use in any particular risk evaluation, or in each and every risk evaluation. Nowhere in the statute does Congress modify "conditions of use" with "all." EPA has the discretion to interpret the term. It cannot apply this discretion in such a manner, however, as to undercut the operation of the statute or to make it impossible for EPA to meet its statutory objectives of throughput and quality.

[3] 82 Fed. Reg. at 7565.

B. Scoping Necessarily Requires EPA to Select Relevant Conditions of Use for Inclusion, and Scope Accordingly.

LCSA requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under certain circumstances called "conditions of use."[4] Conditions of use are defined as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." The legislative text did not direct EPA to include "all" conditions of use.

The statute creates a scoping process that precedes the risk evaluation itself. For a scoping process to have any reasonable meaning, it must actually "scope" -- on a case by case basis, it must determine which conditions of use are appropriate for inclusion because they are relevant and meaningful to the risk evaluation process. EPA's plan to universally include "all conditions of use" all the time in every risk evaluation is contrary to common sense, conflicts with and undermines the statutory design of TSCA as amended by LCSA, and would lead to an absurd result.[5]

EPA's preamble acknowledges the value of scoping (also called problem formulation) in citing the National Academy of Sciences (NAS) National Research Council (NRC) Science and Decisions Report. The NAS report recommended that EPA focus on the "important roles of scoping or problem formulation so that a risk assessment will serve a specific and documented purpose" [emphasis added].[6] The preamble cites an additional NAS recommendation to EPA that the Agency "develop risk assessments that are well-tailored to the problems and decisions at hand so that they can inform the decision-making process in the most meaningful way." We agree, and urge the agency to apply these recommendations to the scoping process.

C. The Legislative Text Acknowledges that What EPA Will Consider and Include in a Given Scope Necessarily Varies.

The scoping provision requires identification of those conditions EPA "expects to consider,"[7] a clause that would be unnecessary if EPA were directed to simply include "all" conditions of use in a risk evaluation.[8] The future tense also acknowledges that EPA might subsequently change

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[4] TSCA § 6(b)(4)(A).

[5] See Massachusetts v. EPA, 549 U.S. 497, 531, 535 (2007) addressing EPA's application of its Chevron deference to particular statutory constructions: EPA not required to regulate "all" greenhouse gases as "air pollutants" everywhere that term appears in the statute; EPA must ground its reasons for action or inaction in the statute; agency regulation cannot conflict with statutory design, and law cannot be read to compel EPA to regulate in a manner contrary to "common sense."

[6] 82 Fed. Reg. at 7265.

[7] TSCA § 6(b)(3)(D).

[8] Before LCSA was enacted, EPA had published multiple problem formulations under the TSCA Work Plan. EPA explained that its problem formulations served as a means for explaining the scope of a risk assessment: "A problem formulation and initial assessment document will serve to inform the public and other interested stakeholders about EPA's initial scoping of findings and plan for any further risk assessment. Problem formulation and initial assessment is the analytical phase of the assessment in which the purpose for the assessment is articulated, the problem defined and a plan for analyzing and characterizing risk is determined." Many of those completed problem formulations were for limited conditions of use. Like other aspects of the TSCA Work Plan, Congress

its position with respect to what conditions of use to include or exclude. Notably, this construction affords EPA the discretion to include all conditions of use where necessary.

This is consistent with congressional intent. Speaking about the compromise bill that was signed into law, Senator Vitter said that EPA "is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical." This discretion and flexibility "assures that the Agency's focus … is on conditions of use that raise the greatest potential for risk" particularly given that "many TSCA chemicals have multiple uses – industrial, commercial and consumer uses" and EPA is "well aware that some categories of uses pose greater potential for exposure than others and that the risks from many categories of uses are deemed negligible or already well controlled."[9]

D. EPA Should Expressly Exclude Substances that Are Not Regulated Under TSCA from the Scope of Risk Evaluations.

TSCA excludes a number of chemical categories from its statutory scope. LCSA did not change these; accordingly, these categories should not be considered for inclusion in any risk evaluation undertaken pursuant to Section 6:

(i) [a]ny mixture,
(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide;
(iii) tobacco or any tobacco product,
(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),
(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [i.e., firearms and ammunition]…
(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The risk evaluation rule should expressly clarify that because these categories are excluded from the definition of "chemical substance" under TSCA, and they are outside EPA's legislative authority to regulate, they therefore excluded from the scope of risk evaluations under Section 6.

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contemplated that problem formulations from the TSCA Work Plan would serve as the model for EPA actions under the amended TSCA. In this case, the problem formulations were to be the model for the scoping exercise under Section 6(b)(4)(D). This is a strong indication that Congress authorized EPA to determine which conditions of use it would evaluate in a risk evaluation by defining the scope appropriately.

[9] Senate Congressional Record, June 7, 2016, at S3519; available at https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf. Mr. Vitter also clarifies that unreasonable risk/no unreasonable risk determinations made pursuant to the risk evaluation are made use-by-use: "[T]o be clear, every condition of use identified by the Administrator in the scope of the risk evaluation must, and will be either found to present or not present an unreasonable risk." Id. at S3520.

Likewise, the rule should clarify that chemical uses within these exclusions are "conditions of use" that are outside the scope of any Section 6 risk evaluation.

In addition to TSCA, which was modernized by the passage of LCSA in 2016, there is a network of statutes in place regulating the safety of chemicals in various venues and applications. Several other federal statutes are in place to regulate chemicals in products and during activities such as workplace manufacturing. Notably, the Consumer Protection Act, Consumer Product Safety Improvement Act, and the Federal Hazardous Substances Act regulate chemicals in a suite of consumer products, including children's products and toys, and the Occupational Safety and Health Act (OSH Act) regulates chemicals in the workplace.

Chemicals in uses regulated by other federal laws and agencies are often referred to as "non-TSCA" uses. EPA should not include these uses in its risk evaluations under TSCA. In rare cases where inclusion might be justified, the Agency should establish criteria to justify including non-TSCA uses in its risk evaluations and should articulate the steps it will follow to ensure adequate interagency consultation and review at the scoping stage. We discuss this topic in more detail below.

E. EPA Should Generally Exclude OSHA-Regulated Uses from the Scopes of TSCA Risk Evaluations.

Although LCSA specifically includes "workers" as a possible category of "potentially exposed or susceptible subpopulation," it does not designate "workers" as a default category. Any consideration of worker exposure must begin with the recognition that worker exposures are regulated under the OSH Act. Given that Occupational Safety and Health Administration (OSHA) standards are in place for the very purpose of regulating risk to worker populations, it should be the unusual case where unreasonable risk may present to a worker population under conditions of use (e.g., use of personal protective equipment).

Importantly, although Congress recognizes under LCSA that it may be appropriate, under particular circumstances, for EPA to designate workers as a potentially exposed or susceptible subpopulation under TSCA, and to regulate workplace exposures, Congress did not amend the OSH Act at the same time that it amended TSCA. Congress also left Section 9(d) of TSCA intact. This section requires EPA to consult and coordinate with OSHA "for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements on those subject to [TSCA] and for other purposes." EPA should ensure that this consultation occurs before risk evaluations are scoped; in cases where worker exposures do not present a significant risk of health impairment under current conditions of use, EPA should decline to include worker populations within the scope of the risk assessment as unduly burdensome and duplicative. This process will help focus risk evaluations and reduce the resource cost to the Agency.

Following this consultation, if OSHA agrees that EPA-led risk evaluation considering worker exposures is necessary (and not otherwise duplicative), EPA should describe the process it used to consult with OSHA and the basis for its findings in the scope of the risk evaluation.

F. EPA Should Generally Exclude Low Exposure Conditions of Use from the Scopes of TSCA Risk Evaluations.

In the prioritization process, certain scenarios may emerge that are low- to no-exposure. An example is a closed system, intermediate chemical manufacture or processing at an industrial site, where worker exposure is well documented and controlled, and does not present a significant risk. A second example would be *de minimis* levels of an impurity in a consumer product, where the levels and variability are well documented and well understood, and exposures are so low as not to present a significant risk. In such cases, it should be apparent in the prioritization process or before scoping that these use scenarios can readily be excluded from the scope of the risk evaluation.

G. EPA Should Apply the "Reasonably Foreseen" Provision as a Focusing Tool to Help Tailor the Scope of Risk Evaluations – Not to Expand Them.

The statutory definition of "conditions of use" is "the circumstances, as determined by the Administrator, under which a chemical substances is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."[10]

The phrase "intended, known, or reasonably foreseen" limits the conditions of use that may be identified and included in a scope. Clearly, if a particular use is not intended, known, or reasonably foreseen, it is not a statutory "condition of use" and may not be included within the scope of a risk evaluation.

The term "intended" is generally well understood to mean intended by the manufacturer or processor. Intention can be demonstrated through express (e.g., a statement to that effect in a premanufacture notice) or implied evidence (e.g., marketing materials that imply a potential application for the chemical). The term "known" is often considered a backstop for the term "intended," in that manufacturers or processors may not "intend" or support a particular downstream use for a chemical but may have actual or imputed knowledge that a chemical is being used in that application.

The definition of "conditions of use" also includes the term "reasonably foreseen." The concept of reasonable foreseeability is well understood in American and western[11] tort law. Foreseeability is "the determinant for the limits of duty under a conventional risk analysis" [emphasis added].[12] Foreseeability is modified by "reasonably," which makes clear that not every conceivable or speculative use is included. Product misuses and illegal uses, and manufacturing that disregards legal and industrial hygiene requirements, are not "reasonable" and thus not "reasonably foreseen."

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[10] TSCA §3(4).

[11] See, e.g., ANNEXURE T, The Concept of Limited Liability, Existing Law and Rationale (Australia), referring to the limiting tests of reasonable foreseeability and proximity, available at http://www.dpc.nsw.gov.au/__data/assets/pdf_file/0012/11406/T.pdf

[12] Tyrus V. Dahl Jr., Strict Products Liability: The Irrelevance of Foreseeability and Related Negligence Concepts, 14 Tulsa L. J. 338, 343 (1978).

There is a doctrine of "foreseeable misuse" in products liability law, as described in Sections 2(b) and 2(c) of the Restatement of Torts.[13] The purpose of this codification is to allow injured parties an avenue to obtain relief where they have misused a product in a way that the manufacturer should have anticipated. The doctrine, however, presents many fact-based questions for a jury. Generally speaking, foreseeable misuses do not include circumstances where the hazard was clear and a plaintiff disregarded it anyway (e.g., the plaintiff decided to juggle knives knowing that they are sharp and not intended for juggling); where instructions and warnings were clear and a plaintiff disregarded them anyway; where a plaintiff had the skills, knowledge and training to act prudently and failed to do so.

In short, in tort cases, "reasonable foreseeability" is the limit of liability. Courts seek to predict reasonable and expected conduct under the specific factual circumstances presented. Here, EPA is tasked with making much the same analysis. Reasonably foreseen conduct therefore does not include illegal uses or activities, product misuses, and illegal and improper disposal. Such conditions of use are properly outside the scope of a risk evaluation.

This approach is sensible and practical. The purpose of the scoping exercise is to focus the risk evaluation. Including every conceivable scenario, regardless of substantiation, likelihood, and severity whereby someone might misuse or be injured by a chemical substance cannot be the point of a risk evaluation. Indeed, boundless approaches ignore the "reasonably" in "reasonably foreseen." This approach to "reasonably foreseen" also becomes untethered from Congress' focus on risk in risk evaluations; rather than focusing on major risks it chases minor, abstract, and even merely hypothetical ones. It undermines the point of scoping the risk evaluation to achieve this purpose, and is inconsistent with Congress' expectation set out in the legislative history that misuses are outside the scope of risk evaluations.[14]

H. EPA Must Use High Quality, Best Available Information to Identify Conditions of Use For Inclusion in Scoping.

Commodity chemicals and building block chemicals may have hundreds or thousands of discrete and readily identifiable uses. In some cases, "major" intermediate and end uses of chemicals will be readily apparent from reporting already made to EPA or other credible sources of public information. Information of varying quality, integrity, credibility, and reliability is available about "uses" of chemicals on the internet, social media, and online journals. A significant amount of information available over the internet is from anonymous sources or anecdotal in nature. EPA should apply its Quality System[15] to information collected and evaluated to identify conditions of use in the pre-scoping stage, and ensure that it has conducted a data assessment to verify that they are of sufficient quantity and adequate quality for their intended use (to define the scope of the risk assessment).[16]

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[13] Restatement (Third) of Torts: Prod. Liab. §§ 2(b), 2(c) (1998).
[14] ''Conditions of Use'' is … not intended to include ''intentional misuse'' of chemicals." S Report 114-67 at 7 (June 18, 2015).
[15] https://www.epa.gov/quality
[16] See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency (EPA Information Quality Guidelines), Section 4.1, available at https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf

Data quality assurance to confirm identified conditions of use should occur before the scope is released, and certainly must occur before the scope is published as final. It is essential to the quality and integrity of the risk evaluation itself. Use of poor quality or outdated information to "identify" conditions of use taints the ultimate science-based decisions required in the risk evaluation and undermines the statutorily-required application of best available science to exposure assessment.

EPA should describe the process it uses to identify conditions of use in the scope of the risk evaluation, including:

- The source of the information about a condition of use;
- The reliability of the source of information (e.g., whether the information is a first-party, anecdotal report (blog, social media post, product comment or review) or reported to a government or credible third party);
- A description of the Agency's assessment of whether the identity of the source of information is known and verified;
- A description of how the information source has been verified and validated, if appropriate; and
- Whether the information is current.

I. EPA Should Not "Lock Down" Conditions of Use at the Time of Scoping.

The Agency simultaneously insists that it must consider "all conditions of use" in the scope of the risk evaluation, but that it will then not actually consider "all" conditions of use through use of a "lock down" procedure, freezing the conditions of use at the time of scoping. In other words, if a new condition of use is discovered or emerges after the scope is published, EPA will not include it in the risk evaluation, regardless of impact. EPA proposes this "lock down" to help the Agency meet its statutory deadlines.[17]

We think the Agency has this backwards. To stay on its statutory schedule – or to move more quickly - the best tool EPA has available is scoping (the ability to scope its risk evaluations in a flexible manner to focus on the conditions posing the greatest potential risk). EPA should propose a process that allows the Agency to take full advantage of this important tool on a case-by-case basis. EPA should be able to select the conditions of use that it believes are most relevant and meaningful to human health and environmental risk and proceed accordingly.

Likewise, EPA should not commit to "locking" conditions of use at the time of scoping. If EPA has discretion to select the conditions of use that it will include in the scope of a risk evaluation – which it does – then EPA should have the companion ability to remove or add a condition of use as circumstances warrant.[18] For example, following scoping EPA might determine that reports of an isolated use were wrong – and that the condition of use does not actually exist. It would

[17] This proposal leaves in limbo the regulatory status of conditions of use that are excluded from the review. If EPA were to implement this approach, it would also need to clarify that excluded conditions of use go back to the prioritization process, and would also need to clarify that they do not have a high priority designation. This approach is also completely inconsistent with EPA's approach taken for manufacturer-requested evaluations.
[18] Similarly, EPA has a companion ability to redesignate low priorities or high priorities as warranted.

make little sense to continue evaluating that condition of use in the risk evaluation. Otherwise, EPA's final risk evaluation would be of suspect quality, integrity, and reliability.

A better approach would be for EPA to articulate in the rule that after a scope is published, EPA retains discretion to modify it upon a showing of substantial need or changed circumstances, or is otherwise warranted because the addition or removal of a condition of use, properly substantiated, will significantly affect the conduct of the risk evaluation.

J. EPA Must Remove the Comment-or-Waive (Issue Exhaustion) Proposal.

EPA further proposes that it can keep risk evaluations on schedule, notwithstanding its proposal to include "all conditions of use" in every scope, by "providing opportunity for comment on the scoping document and specifying that any objections to the draft scope document are waived if not raised during this process."[19] We urge the Agency to remove this issue exhaustion (waiver) requirement for several reasons.

First, it places an unfair burden on the regulated community. A particular company may not be aware, or otherwise in a position to verify, particular end uses that the company does not support (i.e., a downstream value chain to which it does not sell). A company likewise may not be able to verify occurrences of a chemical from natural sources or the actions of third parties through combustion, spills and discharges, disposal, manufacturing practices or incidents, and the like. When EPA insists on including "all conditions of use" in the scope of a risk evaluation, it moves well past the "major" uses of a chemical and "major" sources of exposure to include fleeting, incidental, minor, isolated, or exceptional cases. Information about these "minor" sources of exposure may be well outside the first-hand knowledge of a manufacturer or processor, making it difficult or impossible to offer meaningful comment during the scoping period.

Second, participation in notice and comment rulemaking is governed by the Administrative Procedure Act (APA) and the judicial review provisions of Section 19 of TSCA. Issue exhaustion requirements can be imposed by statute. Notably, there are only a few statutory issue exhaustion provisions in environmental statutes, the most notable of which is in Section 307(d)(7)(b) of the Clean Air Act. There are none in TSCA.

Congress had the opportunity to impose an issue exhaustion requirement for the scope of a risk evaluation in LCSA amendment – and declined to do so. EPA cannot, by regulation, impose an issue exhaustion requirement that trumps the statutory rights and obligations of stakeholders under the APA and TSCA Section 19.[20] Indeed, ACC believes a waiver provision such as that proposed by EPA may not meet Constitutional muster.

Third, the proposal does not rationally advance its claimed purpose – to meet statutory risk evaluation deadlines. An issue exhaustion requirement is supposed to serve two purposes: it

[19] 82 Fed. Reg. at 7566.

[20] Administrative issue exhaustion requirements are largely creatures of statute, and here we have no such statutory construct. While some agency regulations set out issue exhaustion requirements without a statutory mandate, these tend to be in administrative appeal situations or proceedings that are analogs to adversarial litigation. Notably, the LCSA amendment removed a procedure for formal TSCA hearings.

protects administrative agency authority and promotes judicial efficiency.[21] But here, by requiring inclusion of "all conditions of use" in scopes, the agency impairs the ability of industry to meaningfully comment in the limited time available. EPA seems to be of the view that it would rather include "too much" in a scope than inadvertently omit a condition of use and include "too little," but it is the overly broad, unrefined scope that expands the scale and cost of risk evaluations and slows them. EPA then ties its own hands by proposing to "lock down" overly broad scopes, impeding its ability to update or modify them later in the process. This does not advance efficiency or transparency in the regulatory process.

EPA can avoid these inefficiencies by offering a simple process to identify those major, important conditions of use that are most relevant and meaningful to a high-quality risk evaluation – and to use flexibility in designing the scope accordingly. EPA should offer a rationale of why it selected the uses it did in the scope itself.

II. EPA Must Describe How and When it Will Apply Section 26 Requirements to Risk Evaluations.

Section 26(h) sets out scientific standards that apply to every "decision based on science" while EPA carries out risk evaluation under Section 6 [emphasis added]. Section 26(i) requires EPA to "make decisions" under Section 6 based on the weight of the scientific evidence [emphasis added]. A decision would include any judicially reviewable determination, but also any other decision that requires application of science or scientific judgment by the Agency.

EPA should articulate in the risk evaluation rule, at a minimum, the key decision points that will require compliance with Section 26 requirements. These should include, but are not limited to:

- The proposed scope and final scope for risk evaluation
- Hazard assessment , including, where applicable, the likely operable mode of action
- Exposure assessment
- Selection and evaluation of technical procedures, measures, methods, protocols, methodologies, and models
- Basis for scientific assumptions
- Selection and evaluation of quality assurance procedures
- Decisions regarding variability and uncertainty
- Statistical methods
- The draft and final risk evaluation

EPA should document how it applied Section 26(h) and 26(i) requirements for each decision.

[21] The issue exhaustion proposal does not advance judicial economy either. Determinations of no unreasonable risk, made by the Agency following the completion of the risk evaluation process, are judicially reviewable – but as a practical matter this means that a judicial challenge to such a determination would be unlikely to occur until years after the scope was published (and the risk evaluation completed). Changes to conditions of use, or errors in their identification and inclusion, may not all be evident at the time the scope is originally prepared and published, so applying issue exhaustion at this step makes little sense.

III. EPA's Proposed Risk Evaluation Process Should Offer Greater Specificity Regarding the Use of Systematic Review Approaches.

As discussed in further detail in Section IV of these comments, EPA should articulate a clear regulatory definition of systematic review and commit to implementing a systematic review approach throughout the risk evaluation process. Systematic review is a process to collect and evaluate information in a transparent and reproducible manner.[22] ACC cannot envision any situation where a systematic review definition would unduly restrict the specific science that can be used to conduct a risk evaluation. A systematic review process will allow EPA to be flexible and to adapt with changing science, assuming that the new science meets the necessary high quality standards that are required by LCSA. Articulating a regulatory definition for systematic review is fully consistent with EPA's policy objectives.[23]

RESPONSES TO SPECIFIC QUESTIONS RAISED BY EPA

IV. Responses to Specific Questions Raised by EPA

While EPA is seeking public comment on all aspects of the proposed rule, the Agency specifically requests comments on seven topics. ACC's recommendations on each of these topics are provided below.

Question 1. "Redefining" Scientific Terms

To ensure clarity and consistency, important scientific terms should be clearly defined in the rulemaking.[24] While many of these terms are not novel concepts and are already in use, multiple definitions are in use and may mean different things to different stakeholders. Thus, there is a need for clarity and consistency to ensure that the Agency and all stakeholder groups are using uniform definitions.

For example, EPA notes that extensive descriptions for the phrases "best available science," "weight-of-the-evidence," and "sufficiency of information" can be found in EPA's Risk Characterization Handbook[25] and other existing guidance. However, we are unable to find any clear definitions for "best available science," "weight-of-the-evidence" and "sufficiency of information" in EPA's Risk Characterization Handbook. While there are references to "weight of evidence" and "sufficient information," neither term is clearly described.

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[22] See National Toxicology Program Fact Sheet on Systematic Review, available at https://www.niehs.nih.gov/health/materials/systematic_review_508.pdf.

[23] See 82 Fed. Reg. at 7567 ("Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.")

[24] We do not suggest defining terms in a manner that deviates from accepted scientific understanding, and of course, our suggestions are intended to align with best available science requirements set out in the statute itself.

[25] See https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

Similarly, while EPA's 2005 Guidelines for Carcinogen Risk Assessment discuss what is in a "weight of evidence" narrative, there is no clear definition for what it means to conduct a "weight-of-the-evidence" evaluation.[26] In addition, when discussing "sufficient information," the Guidelines for Carcinogen Risk Assessment note that "[g]enerally, 'sufficient' support is a matter of scientific judgment in the context of the requirements of the decision maker or in the context of science policy guidance regarding a certain mode of action."[27] Neither of these definitions is of sufficient clarity to inform stakeholders as to the meaning of the terms that EPA will be using to inform risk evaluation under LCSA.

Although EPA suggests generally that these terms will evolve over time and continue to change, the Agency points to no particular term and offers no explanation why it believes the meaning of a term will change. ACC struggles to think how these definitions may change. While the data sets used to inform some definitions surely change with advances in high-throughput and high content methodologies, ACC cannot identify instances where these definitions have changed. For example, in 1996, Congress emphasized, and described, using the "best available scientific evidence" for risk information in amendments to the Safe Drinking Water Act (SDWA).[28] We can think of no examples where this description has needed to be modified in the last 20 years, and the description appears to have created no problems for the Agency. Nevertheless, even if there were to be a need to change specific definitions if a term became a problem for the Agency, there is nothing that stops EPA from updating and modifying the definition in a future rulemaking.

As requested by EPA, below we suggest specific definitions or definitions which are alternatives to the language EPA has provided. ACC is not proposing to "freeze" the science, and indeed best available science depends on the converse. Scientific advancements will be important to ensuring the effective and efficient implementation of the LCSA. Each of the definitions below allows for scientific inputs and approaches to evolve and improve over time to inform chemical risk evaluations.

i. Best Available Science.

ACC suggests the following definition:

> *Best available science* means information that has been evaluated based on its strengths, limitations and relevance and the Agency is relying on the highest quality information. In evaluating scientific information, the Agency will also consider the peer review of the science, whether the study was conducted in accordance with sound and objective practices, and if the data were collected by accepted methods or best available methods. To ensure transparency regarding best available science, the Agency will describe and document any assumptions and methods used, and address

[26] See EPA's 2005 Guidelines for Carcinogen Risk Assessment, at 2-49, available at https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.
[27] Id. at 2-42.
[28] See 42 U.S.C. § 300g-1(b)(3)(A, B).

variability, uncertainty, the degree of independent verification and peer review.

In proposing this definition, ACC has drawn language directly from the 1996 SDWA amendments[29] and from section 26(h) of the LCSA. EPA has already adopted the language from the SDWA amendments in the EPA Information Quality Guidelines.[30] In addition, the concept of evaluating data based on strengths and limitations is consistent with the definition provided in the Senate Congressional Record for LCSA.[31] To ensure a greater level transparency that forces EPA to "show its work," as was envisioned by the authors of the LCSA,[32] this definition covers not only what EPA must consider and evaluate, but also requires that important descriptions and documentation be including in EPA work products developed under Sections 4-6 of TSCA.

ii. Weight of the Evidence (WoE).

ACC suggests the following definition:

> *Weight of the evidence* means a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

ACC agrees that the term WoE has meant different things to different groups. In fact, different NAS studies contradict themselves regarding the use of this term and inconsistently define its meaning. As such, it is critically important that EPA clearly explain what this term means to the Agency. This term cannot and should not be avoided or discounted as Section 26(i) of the LCSA codifies the requirement for EPA to use a WoE approach. As such, a clear and transparent definition is critical.

ACC is recommending the use of the definition that is in the June 7, 2016 Senate Congressional Record.[33] This is the definition we have provided above. This definition is also consistent with the June 2015 House Report Language.[34] While other definitions exist, using the definition associated with LCSA makes the most sense and is a straightforward approach that is clearly linked to the intent of Congress.

Without a clear definition, WoE will continue to mean different things to different experts and stakeholders. An example illustrates that EPA very recently has not interpreted WoE in the same way Congress now intends. In the draft risk assessment of 1-bromopropane (released prior to enactment of LCSA), EPA does not provide information regarding the quality of the individual

[29] Id.
[30] See generally, EPA Information Quality Guidelines.
[31] Senate Congressional Record, June 7, 2016 at S3518.
[32] Id. at S3522.
[33] Id at S3518.
[34] See House Report, at 33, available at https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.

studies.[35,36] Although the assessment identified some quality considerations, EPA did not provide any information regarding its own findings from its quality review of the individual studies.[37] Additionally, no information was provided to describe how quality, relevance, and reliability considerations were applied and what constitutes a study of "high quality" or "good quality." EPA simply chose the value that provided the lowest point of departure and thus would be most health protective. While EPA staff stated that they followed a WoE approach,[38] picking the lowest point of departure, without an explicit consideration of study quality, is not consistent with a WoE approach. Until there is one clear definition, confusion such as this will likely continue and this confusion will stifle the scientific dialogue.

iii. Sufficiency of Information.

ACC suggests the following definition:

> *Sufficiency of information* means that, taking into account the importance of the determination, the Agency has appropriatel y relied on the best available science, considering the weight of the scientific evidence to make a reasoned and transparent fit-for-purpose determination.

This definition is important as EPA uses this term repeatedly in the preamble of the proposed rule to describe scientific information. We have provided a definition that ties this information directly to the best available science and weight of the evidence standards required in Section 26 of the LCSA. If no definition is provided, stakeholders are left guessing as to what standards will define sufficient information.

In the preamble of the proposed rule, EPA uses related terms including "scientifically valid information" and "sufficient quality." These terms must also be defined. ACC suggests the following:

> *Scientifically valid information* means information that the agency has considered the quality , reliability, and relevance of the information for the decision being made. Consistent with the Agency Assessment Factors Guidance (2003) evaluation of i nformation will include the consideration of the soundness, applicability and utility, clarity and completeness, uncertainty and variability and evaluation and review of the information.

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[35] See Comments of the American Chemistry Council on the TSCA Work Plan Chemical Draft Risk Assessment of 1-Bromopropane, Docket No. EPA-HQ-OPPT-2015-0084, May 9, 2016.

[36] See Chemical Safety Advisory Committee Minutes No. 2016-02, at 41, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0805-0028 ("While the Agency indicates that the literature was thoroughly reviewed for robustness, adequacy, etc., the Committee found that it is not clear what exact methodology was used to systematically rate, rank, and select studies to inform sections of the risk assessment. For example, was a quantitative ranking system developed for study quality?")

[37] See TSCA Work Plan Chemical Risk Assessment Peer Review Draft, at Appendix M, available at https://www.epa.gov/sites/production/files/2016-03/documents/1-bp_report_and_appendices_final.pdf.

[38] See Chemical Safety Advisory Committee Meeting Transcript, at 130, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0805-0027.

Sufficient quality means that the Agency has relied on scientifically valid information to make the determination.

These definitions are consistent with existing Agency guidance. However, to improve transparency and consistency, it is important that EPA clearly define these terms in the final rulemaking.

iv. Unreasonable Risk.

ACC agrees with EPA that a single definition of unreasonable risk is not workable due to the variety of factors that are necessary to consider when making an unreasonable risk finding. However, the risk evaluation rule should list the considerations that must be taken into account in making that finding. More importantly, EPA should commit to describing and transparently presenting how each of these considerations impacted the unreasonable risk finding. The descriptions that support the unreasonable risk finding should be presented in the draft and final risk evaluation documents. ACC suggests the following description be included in the preamble to final rule:

> *Unreasonable risk* means that the Administrator has considered relevant factors, including the effects of the chemical substance on health and the magnitude of human exposure to such substance under the conditions of use; the effects of the chemical substance on the environment; and the magnitude of environmental exposure to such substance under the conditions of use. Factors considered to reach this risk-based determination may include: characterization of cancer and non-cancer risks (including margins of exposure for non-cancer risks and mode of action analyses for cancer risks), characterization of environmental risk, the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard), the irreversibility of hazard, and uncertainties associated with the analyses and data.

This description is generally consistent with the considerations EPA has provided in the proposed rule, and adds a consideration to ensure that environmental risk findings are also considered. Notably, however, EPA inappropriately includes cumulative exposure in its list of considerations.[39] This should be removed. LCSA does not require the consideration of cumulative exposure in the risk evaluation process. Further, there is no generally accepted approach to inform the scientific methods, inputs and tools to evaluate cumulative risk. While EPA and other agencies continue to work on guidance in this area, scientifically robust draft frameworks for the evaluation of cumulative exposure risks are non-existent.

v. Reasonably Available Information.

ACC supports a clear definition of "reasonably available information;" however, we offer specific suggestions (shown in strikethrough and underline) to improve the definition EPA has provided:

[39] 82 Fed. Reg. at 7566.

Reasonably available information means ~~existing~~ information that EPA possesses or can reasonab ly obtain and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Confidential Business Information provided to the Agency will be treated as reasonably available information.

ACC suggests these edits because it is important that EPA be clear that it will include confidential business information (CBI) in its consideration of relevant information in a risk evaluation. While this information must be protected from public disclosure, it may provide important exposure and use information that the Agency should rely upon during the risk evaluation process.

ACC suggests deleting the term "existing." Due to the advancement of high throughput technologies and *in vitro* methods, it may be feasible and appropriate for EPA to obtain useful *de novo* information in a very short amount of time, thus making it easily useable and accessible considering the deadlines specified in LCSA. For example, in 2010, EPA used *in vitro* ToxCast methods to rapidly generate data on oil spill dispersants.[40]

Similarly, in responding to health and environmental concerns related to the chemical spill in the Elk River in West Virginia in 2014, the National Institute of Environmental Health Sciences (NIEHS) conducted a battery of tests which included short term high throughput screening assays and other *in vitro* assays which were able to generate useful information in a very short period of time.[41] This information was then shared with EPA and other stakeholders to inform the evaluation of risks.

EPA should be clear that this definition implies that data and information, including robust summaries, made available by other regulatory bodies, including international agencies (such as the World Health Organization International Programme on Chemical Safety) and national authorities from other countries (such as the European Union and Canadian government chemical evaluation programs) are considered reasonably available information. This information can inform not only risk evaluation, but also prioritization. The International Uniform Chemical Information Database (IUCLID)[42] is just one example of a robust database of chemical specific information that EPA should be using when reviewing available data on individual chemistries.

Question 2. Margin of Exposure

ACC strongly supports the margin of exposure (MOE) approach for use in the risk evaluation process. This approach is far more transparent than a hazard index or hazard quotient (HQ) approach where the application of uncertainty factors is not transparent and often not scientifically justified. In addition, this approach is consistent with the way non-cancer hazards are currently evaluated, not only within EPA but throughout the Federal government. ACC

[40] See Judson, RS, et al. 2010, Analysis of Eight Oil Spill Dispersants Using Rapid, In Vitro Tests for Endocrine and Other Biological Activity, Environ Sci Technol. 44(15): 5979–5985, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2930403/.
[41] See https://ntp.niehs.nih.gov/results/areas/wvspill/collective.html.
[42] See https://echa.europa.eu/-/more-information-to-be-published-from-reach-registrations.

recognizes that the current MOE approach, similar to the HQ method, creates difficulties for the analysis of costs and benefits; however, it provides an accurate representation of the current state of the scientific approach for evaluating non-cancer hazards. While some have suggested a "linear to zero" approach for non-cancer hazards, it is not a generally accepted scientific approach, and in fact is not supported by an evaluation of biochemical networks.[43] It can be considered a policy decision and as such should be made on a case-by-case basis considering the specific supporting information for an individual chemical hazard. It should not become a new default approach.

When EPA presents MOE exposure values, consistent with EPA's 2000 Risk Characterization Handbook[44] and the EPA Information Quality Guidelines, EPA should present a range of estimates including the central tendency estimate. While EPA tends to present ranges reflecting different exposure scenarios, the range of values presented should be informed by modifying both the exposure and the hazard estimates.

Question 3. Systematic Review

EPA notes in its proposal that it has conducted systematic reviews in the past and that it intends to do so in the future. The Agency has not, however, made a firm commitment to follow a systematic review approach and seeks comment on whether such a commitment in regulatory text is necessary. ACC strongly supports the need for regulatory text describing the systematic review process, and EPA should commit to conduct its risk evaluations consistent with the systematic review definition.

Systematic review is critical part of a WoE approach. As discussed above, it is part of the definition provided in the June 7, 2016 Congressional record and the June 2015 House Report.[45] Congressional intent is to ensure that EPA conducts systematic reviews is clear.

ACC acknowledges that systematic review can mean different things to different groups. A recent publication by Haddaway et al. found that while systematic review is becoming the "widely accepted gold standard in evidence synthesis" not all users of systematic review understand the term in the same way.[46] In this publication, a survey of six publications that claimed to be systematic reviews found that none met all the requirements of a true systematic review.[47] For instance, simply having a system to search for studies does not classify as being a systematic review. Haddaway et al. state:

> A review may include a systematic search or screening, but unless it includes all of the aspects of a full systematic review, such as critical appraisal and full transparency, the

[43] See https://ehp.niehs.nih.gov/1408244/.
[44] See https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.
[45] See Senate Congressional Record, June 7, 2016 at S3518; House Report at 33.
[46] See Haddaway, NR, et al. 2016. "A Little Learning Is a Dangerous Thing": A Call for Better Understanding of the Term 'Systematic Review,' Environ Int 99: 356-360, available at: http://www.sciencedirect.com/science/article/pii/S0160412016303634.
[47] Id.

> review reliability is reduced and it cannot be referred to as systematic….It is unhelpful to classify "narrative reviews" as systematic reviews...[48]

EPA states that it has included systematic reviews in the past; however, it is not clear what exactly it has done and where these reviews can be found.[49] The last completed draft TSCA Work Plan risk evaluation was for 1-bromopropane. The executive summary of the peer review report of this draft evaluation, dated August 22, 2016, states:

> Committee members agreed that the 1-BP risk assessment (and other TSCA chemical assessments to be presented in the future) would benefit by adoption of systematic review practices to increase the transparency of how studies were selected and evaluated. For example, the Committee recommended that it should be explicitly stated what criteria were used to determine "the monitoring was adequate and of acceptable quality" (risk assessment document, page 44). The Committee also noted that it would be useful to reference studies that were evaluated but did not meet baseline criteria to inform the exposure estimates.[50]

In addition, the peer review committee could not determine "what exact methodology was used to systematically rate, rank, and select studies to inform sections of the risk assessment."[51] Peer reviewers also could not find any ranking system developed for study quality.[52]

It is critically important that systematic review mean the same thing to all engaged stakeholders, including Agency staff and peer reviewers. ACC cannot envision any situation where a definition of systematic review would unduly restrict the specific science that can be used to conduct a risk evaluation. A systematic review process will allow EPA to be flexible and to adapt with changing science, assuming that the new science meets the necessary high quality standards that are required by the LCSA. Including a regulatory definition for systematic review is fully consistent with EPA's policy objectives.[53] As such, ACC recommends the following definition be included in the final rule:

> *Systematic review* means that the evidence has been evaluated using a predefined, transparent, and reproducible process to identify, apprais e, and synthesize the available body of evidence to answer a specific question. To ensure transparency, systematic reviews should include a Protocol that describes the specific question(s) that will be answered, the literature search strategy and plans for data collection, the methods for evaluating the quality and relevance of the data

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[48] Id. at 4.
[49] See 82 Fed. Reg. at 7572.
[50] See Chemical Safety Advisory Committee Minutes No. 2016-02, at 1.
[51] See id. at 41.
[52] Id. at 42.
[53] See 82 Fed. Reg. at 7567 ("Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.")

(including the specific criteria that will be used), the approach for data analysis and integration and also the plans for peer review.

Question 4. Manufacturer Requests

EPA seeks comment on approaches to using its information gathering authorities (such as Section 8(a) or (d) authorities) to ensure that EPA has the most complete information to make its risk determination for a manufacturer requested evaluation. ACC urges EPA to appropriately use its authority.

In its proposal, EPA indicates that it will not accept a manufacturer request where any of the relevant data is not in the possession of the manufacturer but is "with" another entity. EPA also requires a commitment that manufacturers provide all reasonably available information on hazard and exposure for all conditions of use, even if it is not publicly available.[54] These requirements will make it extraordinarily difficult, if not impossible, for a manufacturer to submit a request acceptable to EPA.

ACC believes it is inappropriate for EPA to require that a single manufacturer contact and extract information outside its possession and control – and for which it has no legal authority to obtain – to be able to initiate a manufacturer requested risk evaluation. It is more appropriate that EPA use its Section 8 authority judiciously to collect information to be able to review and make a determination on a manufacturer requested risk evaluation. There are also instances where other governments (e.g., U.S. state or locality, U.S. government agency), universities, non-profits, or other entities may have information that the manufacturer is unable to obtain. There may even be cases where EPA itself has relevant information to inform a risk evaluation, and a manufacturer is incapable of obtaining it, providing it, or referencing it to EPA. These circumstances should not bar a manufacturer from initiating a request.

Manufacturer requested evaluation are further discussed at Section VIII.

Question 5. Peer Review

EPA requests public comment on whether there are circumstances where peer review might not be warranted. When risk evaluations will lead to findings of unreasonable risk, which will then trigger risk management actions, the draft risk evaluation should always be peer reviewed. As conclusions of "no unreasonable risk" for specific conditions of use may likely be part of the risk evaluation, the science supporting these determinations should also be reviewed to ensure public confidence.

Certainly for the first few years of LCSA implementation, as EPA applies new statutory requirements including the Section 26 scientific standards, risk evaluations will be highly influential. For highly influential scientific assessments, the most robust peer review standards

[54] 82 Fed. Reg. at 7569.

should be followed, including the need for panel review that strives to reach consensus. When the panel review is structured to provide individual opinions in a report to EPA, it resembles a letter review, which is appropriate when a draft document covers only one discipline.[55] As the draft risk evaluations developed under the LCSA will be complex multidisciplinary assessments which integrate both hazard and exposure information, robust expertise will be needed and a more rigorous review process is appropriate.[56] The EPA Science Advisory Board (SAB) strives to reach consensus when conducting panel reviews.[57] Reports in which only non-consensus opinions are provided will not be sufficiently helpful to the agency. They will not reflect scientific consensus and this will undermine both stakeholder and risk manager confidence, subsequently impacting the confidence in future risk management rulemakings. Thus we highly recommend that peer review reports to EPA should provide consensus opinions where possible, with the understanding that non-consensus opinions be included in the rare cases where consensus cannot be reached in a timely manner.

ACC agrees with EPA's approach to release peer review plans along with the draft scoping documents. These peer review plans, which will be subject to public comment, should commit the agency to conducting panel reviews which strive to reach consensus. In addition, the peer review plan should confirm EPA's intent to share a draft charge with the public for comment and input. The peer review plan should also ensure that as part of the process the peer review panel will provide responses to the substantive scientific comments that are received from the public.

Question 6. Reliance on Existing Guidance and Procedures for Conducting Risk Evaluations

EPA is seeking input on its proposal to not "codify" any specific guidance, method or model in the regulatory text. As noted above, ACC believes that EPA must, at a minimum, include the definitions for WoE and systematic review in the regulatory text itself. The uses of these evaluation approaches (or methods) should be required for risk evaluations; these are cross-cutting approaches to evaluating evidence. While the type and quality of evidence available will change and evolve over time, what constitutes a good scientific approach has not changed over time and is not likely to change at any pace which could be characterized as "rapid."

With respect to guidance, it is important that EPA not codify in the rule EPA's guidance documents, many of which are outdated. Much of what is in existing guidance includes default approaches that may be outdated (see discussion below) and many of the recommendations in guidance documents are situation-specific and cannot be universally applied.[58] Due to these limitations, neither should EPA cite a list of guidance documents in scoping documents.

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[55] See Office of Management and Budget (OMB), Final Information Quality Bulletin on Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005).

[56] See id. for further details on this distinction.

[57] See EPA SAB, Advisory Committee Meetings and Report Development: Process for Public Involvement, available at: https://yosemite.epa.gov/sab/sabproduct.nsf/WEBSABSO/part-mtgs-reports/$File/sabso_04_001.pdf ("Ideally, the deliberative process should converge on some sort of consensus conclusion.").

[58] For instance, EPA's 1991 Guidelines for Developmental Toxicity, available at: https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf, state, at 38, "for developmental toxic effects, a primary assumption is that a single exposure at a critical time in development may produce an adverse developmental effect, i.e., repeated exposure is not a necessary prerequisite for developmental toxicity to be manifested." This is an assumption that does not put the science first. If EPA were to invoke this guidance, risk

For instance, simply stating that EPA will follow the 2005 Guidelines for Carcinogen Risk Assessment (Cancer Guidelines) or other EPA guidelines does not provide the public with a sufficient level of specificity or granularity to understand what scientific approach and "accepted science policies" will be followed. As has been documented from years of peer review of some EPA hazard assessments (e.g., IRIS assessments), interpretation of even EPA's Cancer Guidelines can vary from expert to expert. For example, EPA's Cancer Guidelines invoke a linear extrapolation approach as a default in the absence of sufficient scientifically justifiable mode of action information, but there has been considerable variability in both EPA's and experts' determinations of when sufficient information exists to require non-linear modeling. For example, for 1,4-dioxane, Health Canada determined that a threshold approach is appropriate to use for characterizing risks to human health,[59] but, in evaluating essentially the same dataset, EPA IRIS program discounted this mode of action and adopted a liner, no-threshold method.[60] In addition, there are very few "accepted science policies" that all stakeholders can agree upon. For example:

- EPA's Cancer Guidelines specifically state that data should be used ahead of defaults; however, the members of the 2009 NAS Science and Decisions committee supported defaults as adequate and appropriate.

- EPA's Cancer Guidelines recommend using mode of action in a risk assessment; however, the members of the 2009 NAS Science and Decisions committee suggested that one of three dose-response approaches is typically going to be appropriate for use. This default approach recommended by these NAS committee members conflicts with EPA's own guidelines.

Rather than merely point to guidance documents, EPA must be more specific with respsed to its process in the rule itself. In the appendices of ACC's August 24, 2016 comments to EPA to inform EPA's proposed risk evaluation framework rule, ACC provides detailed comments on the elements of specific and important steps within the risk evaluation process (e.g., hazard identification, dose-response, risk characterization, peer review).[61] EPA's scoping document should provide a level of specificity that addresses each of these elements. Just providing a list of EPA guidance documents or NAS reports is not only woefully inadequate, it is not sufficiently transparent for stakeholders to understand the actual scientific approach EPA intends to take to evaluate, analyze data and information, and then integrate all the evidence from mechanistic studies, animal toxicity tests, and human epidemiological investigations for WoE decision making.

EPA also seeks input on whether current guidance documents are sufficient or if additional guidance documents that already exist, but are not noted on a particular EPA website, should be

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evaluations would not be consistent with best available science, which puts actual data and information ahead of default approaches. We also note that this is an example of a guidance document which should be updated.

[59] See http://ec.gc.ca/ese-ees/789BC96E-F970-44A7-B306-3E32419255A6/batch7_123-91-1_en.pdf.

[60] See https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0326_summary.pdf#nameddest=woe.

[61] See ACC comments, at Appendices B-E, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0400-0028.

added.[62] EPA's question is too narrow. EPA should ask the more important question regarding whether or not existing guidance is sufficient. Many of the guidance documents on the cited EPA website are extremely outdated, particularly considering the evolution of the science. For instance, EPA's Guidelines for Mutagenicity were last updated in 1986 and Guidelines for Developmental Toxicity are from 1991. These documents, and others, are over 20 years old and the science has evolved considerably over the last 20-30 years. In addition, when these documents were written they put in place policies which were driven by default assumptions based on a lack of data and a lack of understanding at that time of molecular biology, dosimetry, mode of action pathways, and toxicity mechanisms. Many of these "policies" are essentially default approaches that should be replaced by data and up-to-date 21st century knowledge.

There are areas where current guidance is simply lacking. For instance, EPA's 2006 Framework for Assessing Health Risk of Environmental Exposures to Children states "the integration of toxicity data and children's exposure estimates is an area for which no guidance exists but is needed."[63] As there will likely be cases where children are a susceptible population of concern, this is certainly an area where guidance is needed.

EPA states "EPA may also develop additional guidance(s) for risk evaluation in the future."[64] This statement is inadequate. Section 26(l) of the LCSA requires that by June 22, 2018 EPA develop any policies, procedures, and guidance necessary to carry out LCSA.[65] This section also requires that not later than June 22, 2021, and not less frequently than once every five years thereafter, EPA review the adequacy of policies, procedures and guidance. EPA should immediately begin to engage the public, in an official stakeholder process, to begin identifying areas where guidance should be developed. ACC also urges EPA to begin the process of evaluating all existing risk assessment related guidance documents for accuracy and relevance. Guidance documents that need to be updated should be identified and prioritized. There will likely be a significant amount of guidance that will need to be created and updated within the next two to five years. Assessments that are being started now should be consistent with these new and updated guidance documents. It is in the interest of all stakeholders that EPA's guidance be updated to reflect current science and that all assessments initiated after the enactment of LCSA be developed in compliance with updated guidance.

Question 7. Interagency Collaboration

As discussed in more detail in section I(E) of these comments and consistent with TSCA § 9, EPA is obligated to consult and coordinate with OSHA. EPA must describe the process it uses to consult with OSHA and the basis for EPA's findings in the scope of the risk evaluation.

Ensuring appropriate collaboration with other agencies is as important as it is with OSHA. While EPA notes that it is committed to ensuring engagement and dialogue with interagency

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[62] See 82 Fed. Reg. at 7573.
[63] See EPA 2006 Framework for Assessing Health Risk of Environmental Exposures to Children, at 6-2, available at https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=158363.
[64] See 82 Fed. Reg. at 7570.
[65] See TSCA Section 26(l).

experts, EPA is reluctant to provide a general description of the process and timing it will use.[66] EPA states that codifying a process in the regulation may limit potential interagency collaboration. ACC does not agree. Offering a general description of the interagency collaboration process in the rule would set a baseline which EPA would be free to exceed; it would not limit collaboration.[67] More importantly, it helps explain to stakeholders which agencies will be consulted and when. This transparency helps stakeholders understand what to expect, and it also helps them ensure that relevant information is shared among agencies.

EPA should commit to ensuring an interagency coordination process as soon as a chemical is designated a high priority. At this early stage, interagency coordination should be used to inform the development of the scope document and then to review the scope document. In addition to including OSHA and the National Institute for Occupational Safety and Health (NIOSH) if workplace exposures may be considered, EPA should also include relevant agencies such as the Small Business Administration (SBA) Office of Advocacy and any other agencies that may be impacted by a particular condition of use (e.g., Department of Defense (DOD), Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA)).

EPA should also include other agencies that are members of the National Science and Technology Council's Committee on Environment, Natural Resources, and Sustainability's new Toxicity Assessment Committee. These agencies may likely have chemical-specific knowledge which may inform EPA's risk evaluation. Note, however, ACC does not support the use of the existing OSHA–MSHA–NIOSH–NIEHS–EPA (OMNE) committee. Use of this committee alone excludes important agencies with not only relevant expertise but also potential experience as users of chemicals, such as DOD, DOE, NASA and the SBA Office of Advocacy.

Once the scoping step is complete, the full interagency group should be afforded an opportunity to review and comment on draft risk evaluations before they are released for public comment and before the assessment is finalized. While a risk evaluation is not a regulation, it is an influential science document that will inform regulatory activities, potentially at multiple agencies. As such, interagency review coordinated by OMB may be appropriate. With this approach, a neutral arbiter would be coordinating the review and ensuring that all interagency concerns are voiced and appropriately addressed.

SPECIFIC RECOMMENDATIONS

V. Timelines for Public Comment

The proposed rule describes a risk evaluation process that has three opportunities for public comment. These include a period for comment on draft scoping evaluations, a period for comment on draft risk evaluations, and period to comment on manufacturer submitted requests for risk evaluations. ACC supports these public comment opportunities; however, longer

[66] 82 Fed. Reg. at 7573.
[67] This is to be distinguished from a detailed recitation of when and how agency consultation will occur, which is not necessary.

comment periods are needed to ensure stakeholder engagement and robust well-supported results.

A. Comment Period on the Draft Scope

ACC recommends that EPA allow a period of 60 calendar days for commenting on the draft scope. EPA's proposal of 30 calendar days is far too short to allow for sufficient evaluation of hazard information, exposure information, and planned methods.

For organizations like ACC, time is needed not only for staff to review the draft document, but also to ensure coordination with multiple member companies who will be potentially be impacted by the forthcoming risk evaluation. Time is needed to ensure that comments developed are not only representative, but also constructive and informative to EPA. A 30-day comment period is simply unworkable, particularly if EPA intends to include all conditions of use. EPA will likely also rely on pre-existing evaluations to inform screening level evaluations and a detailed review of this underlying information will take time. As draft scope documents will likely be complex, ACC recommends that the default comment period be 60 calendar days and that extensions of the comment period be allowed only for particularly complex scoping assessments.

B. Comment Period on the Draft Risk Evaluation

Once the scoping evaluation is complete, EPA will likely spend two years conducting the risk evaluation. When the draft risk evaluation is complete, EPA proposes a 30 day calendar period for public comments. ACC recommends that this comment period be at least 90 calendar days. The draft risk evaluation is expected to be a complex, science and data rich evaluation that is the culmination of over two years of work by EPA staff and contractors.

This evaluation will likely also consider multiple populations, including susceptible populations such as workers, and multiple exposure scenarios for each individual condition of use. The document may be made more complex by the fact that EPA may be evaluating multiple conditions of use and, as required by the LCSA, will include a detailed and transparent weight of the evidence evaluation of hazard and exposure information for each condition of use. The data and calculations presented in the document will also need to be scrutinized, and modeling results independently verified. This document will be far more complex than the scoping evaluation and sufficient time will be needed to review, coordinate, and prepare constructive comments for EPA.

EPA must ensure that this public comment period occurs before the draft risk evaluation undergoes peer review as the peer reviewers should be informed by the public comments. In addition, when EPA releases the draft risk evaluation, a draft charge for the peer reviewers should also be released and made available for public comment. The final charge sent to peer reviewers should be informed by and revised, as needed, following public comment on the draft to ensure that the peer review will address areas where there is significant stakeholder disagreement. This approach is consistent with the EPA SAB staff commitment to ensuring that

the committee discusses the charge in a public venue and also ensures that the charge is not unduly narrow.

C. Comment Period on Manufacturer Requested Evaluations

Once EPA receives a manufacturer request for a risk evaluation and deems it to be valid, EPA proposes a comment period of no less than 30 calendar days. ACC is concerned that this open-ended comment period could potentially delay EPA's determinations. Based on EPA's proposal, a valid manufacturer request will need to contain all the exposure and hazard information for multiple conditions of use. The information presented will be similar to what EPA would present in a draft scoping evaluation. As such, ACC recommends that EPA align this comment period with the comment period provided for the draft scoping evaluation. ACC recommends that this be 60 calendar days and that extensions of the comment period be allowed only for particularly complex manufacturer requests.

VI. The Risk Evaluation Process

In describing what the risk evaluation process will look like under the LCSA, compared to previous assessments, EPA notes that key differences include considerations of conditions of use, timelines, and determinations of unreasonable risk.[68] While these are indeed new considerations, EPA fails to mention the importance of relying on best available science and using a WoE approach, which should incorporate systematic review practices. ACC believes that these requirements, from Section 26 of the LCSA, do indeed require a new risk evaluation process—one that is much more transparent, objective and reproducible. ACC has addressed the importance of Section 26 previously in these comments and will focus in this section on the steps in the risk evaluation process.

When generally discussing the risk evaluation process, EPA points to specific NAS committee reports and EPA guidance documents to describe how the Agency will follow "accepted science policies" and approaches. As ACC has discussed previously, in responding to question 6 (see Section IV, above) this approach is not sufficiently transparent and much more specificity will be needed for stakeholders to understand the approach EPA intends to provide in the scoping document.

A. Scoping

EPA's risk evaluation process begins with the development of the scope. In the scope, EPA intends to include the conceptual model and the analysis plan. ACC suggests that this scope also include the literature search terms and results, and a screening level risk evaluation. Consistent with systematic review approaches, discussed above, EPA should ensure that the analysis plan includes the protocol for the systematic review that will be conducted in the refined risk evaluation step.

As shown below in Figure 1, in order to ensure that the in-depth risk evaluation is focused on the conditions of use of greatest potential concern, EPA must use a tiered approach that includes a

[68] See 82 Fed. Reg. at 7565.

screening level quantitative risk analysis in the scope phase. Screening-level assessments require less data and information, and are typically deterministic and based on conservative, health protective assumptions and methods. When a screening assessment indicates low risk for a particular condition of use, the Agency should have a high degree of confidence that the potential risks are much lower than the calculation and, therefore, the actual risks are lower and/or perhaps non-existent. Examples of low risk conditions of use could include occupational uses already regulated under OSHA, *de minimis* uses, or feedstock uses where the use is already regulated, as discussed above in Sections I(D)- I(F) However, when a screening-level risk assessment indicates a potential concern for an adverse effect, this does not mean that the actual risks are significant and warrant action. Rather, it indicates the Agency should take a second step in the risk evaluation process to refine the evaluation to more accurately quantify potential risks.

This tiered, iterative approach is consistent with EPA's exposure assessment practices, where screening level tools, which are "protective by design," may be used initially, and then if needed, higher tier tools, which are "more complex and allow for more realistic exposure assessments" can later be employed.[69]

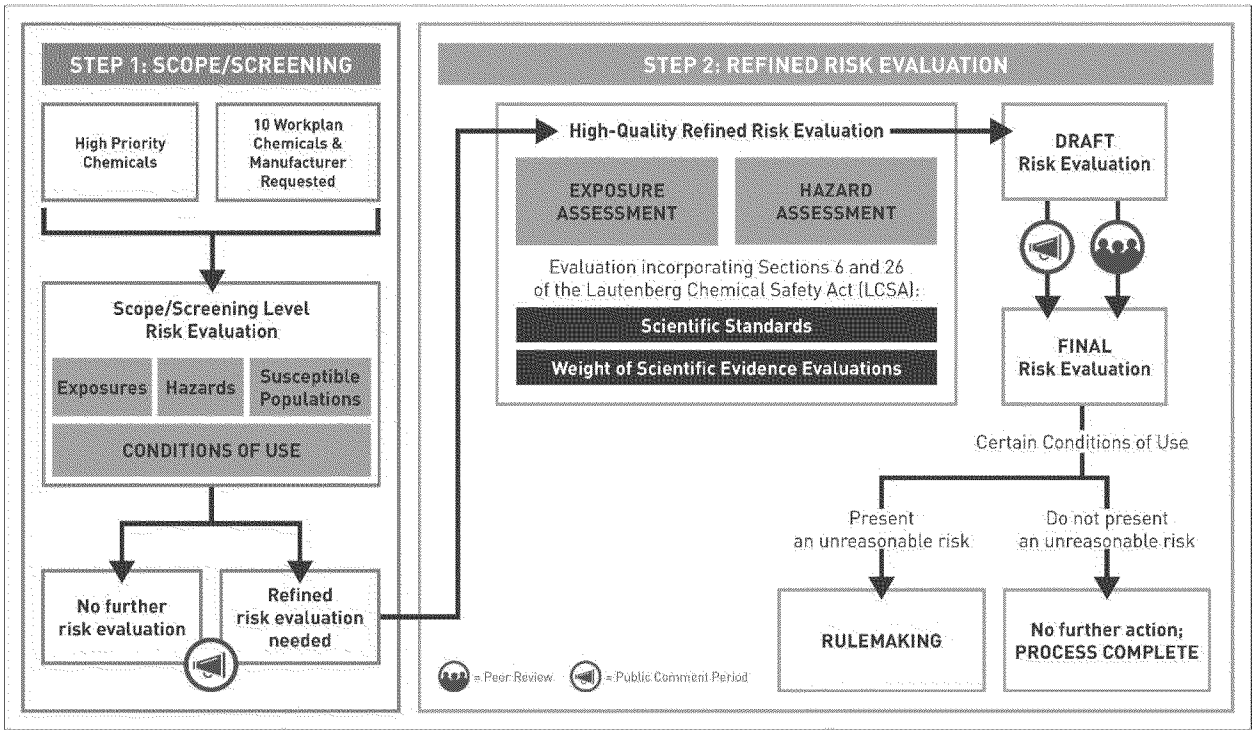

Figure 1. A Two-Step Process for Conducting Risk Evaluations
Note this is a simplified version of the process, see text for more detail

i. Conditions of Use Requiring No Further Evaluation

Once the draft scope is complete, there will likely be conditions of use which will not require any further evaluation as they are unlikely to present an unreasonable

[69] See https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca.

risk to human health or the environment. After EPA takes comment on these findings and finalizes the scope document, EPA should formally announce the conditions of use that "do not present an unreasonable risk."

While EPA may make additional findings of "does not present unreasonable risk" after the refined risk evaluation is complete, for those conditions of use that do not require further evaluation after scoping, there is no reason for EPA to wait the 3 to 3.5 years to complete the refined risk evaluation before announcing these findings. Once announced, the determination of "does not present unreasonable risk" for the specific condition(s) of use should be considered final agency action.

ii. Ensuring Sufficient Information to Conduct a Refined Risk Evaluation

While EPA intends to only conduct risk evaluations on those chemicals for which sufficient information exists, there will likely be a few cases where, once a screening level evaluation is complete, EPA will realize that certain data needs preclude conducting a refined risk evaluation. In such cases, where EPA may need to use test rules, orders or consent agreements to gather existing or new information, EPA should pause the risk evaluation process. This pause will allow the needed data to be generated in a scientifically robust manner. When this is necessary, EPA should announce this pause and its expected length in the Federal Register.

EPA should also use the Federal Register to notify the public when the pause ends and the risk evaluation commences. ACC expects that EPA will not need to pause assessments frequently, but EPA should be aware that there may be cases that necessitate the use of a pause. As ACC discusses in our comments on the Prioritization Framework, during the prioritization process, it is not appropriate for EPA to collect data to conduct full risk evaluations.[70]

B. Refined Risk Evaluation

The additional steps of the risk evaluation process include hazard assessment, exposure assessment, risk characterization, public comment, and peer review. Further details regarding the specific elements that should be in different sections of the risk evaluation are included in the appendices of ACC's August 24, 2016 comments.[71] As they were clearly presented to the Agency and are in the public docket, while they are still relevant, we will not reiterate them here.

While previously emphasized in these comments, ACC reiterates that it will be important throughout the refined risk evaluation process that EPA always rely on the best available science and follow a WoE approach that incorporates systematic review processes.

[70] See ACC comments on the Prioritization Framework Rule, submitted on March 20, 2017.
[71] See ACC comments, at Appendices B-E, available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0400-0028.

Comments on the sections of the risk evaluation process that have not been previously addressed above are presented in this section.

i. Hazard Assessment

When conducting refined hazard assessments for human health or environmental endpoints, EPA must rely on the data (reasonably available information that is scientifically valid, as defined in Section IV of these comments) first and foremost. When additional data are needed, EPA may rely on models and extrapolations. All assumptions and uncertainties associated with these models and extrapolations must be transparently discussed. When EPA is faced with conflicting data or data that could be interpreted in multiple scientifically plausible ways, EPA should strive to present the full range of scientifically supportable analyses for consideration.

As the types of data that will be available for the agency to consider will vary for each chemical and as science advances (e.g., high throughput screening tools), EPA should not specifically mandate the types of data that will be used. There will likely be cases where these data do not exist or are not of sufficient quality.

In addition, EPA states that it will evaluate, as appropriate, "acute, subchronic, and chronic effects during various stages of reproduction or life stage."[72] We urge EPA to ensure that these evaluations are necessary for the relevant conditions of use. Otherwise the Agency will spend too much time focusing on subpopulations or durations that are not relevant or critical to the refined risk evaluation. EPA must also verify that scientifically valid information exists to inform each of these scenarios and that consistent with WoE and systematic review practices, data are evaluated based on their strengths and limitations. The criteria that will be used to evaluate the strengths and limitations of studies from different streams (epidemiologic, toxicologic, mechanistic), should be presented in the protocol that is released with the scope document.

EPA states that dose-response assessments will be included where possible.[73] EPA should describe transparent criteria that will be used throughout the risk evaluation process to determine if the data are of sufficient quality for dose-response assessment. Conducting dose-response assessment on data of inadequate quality will likely lead to misleading and unreliable findings in the risk characterization step.

For environmental hazard assessment, EPA notes that the agency may rely on incident data.[74] ACC cautions EPA on this approach as incident data is very situational specific, requires a deep understanding of the particular situation and may not be of sufficient quality for use in other situations. Therefore, EPA should

[72] See 82 Fed. Reg. at 7579.
[73] Id. at 7571.
[74] Id. at 7579.

judiciously use this information and must be extremely transparent regarding all assumptions and uncertainties when incident data are used.

Similarly, EPA states that the Agency may also consider ecological field data.[75] ACC appreciates that EPA will consider using these data over modeling data as this is consistent with EPA's data preference hierarchy.[76] Consistent with this hierarchy, EPA must ensure that the data are valid, reliable and relevant for the decision being made.

ii. Exposure Assessment

For refined exposure assessment, above all else, EPA must ensure that it is using high quality representative data that are reflective of current uses for the conditions of use that are of concern. Similar to the necessity to clarify how the strengths and limitations of hazard information will be evaluated, EPA should also clearly present the approach that will be used to evaluation exposure information. As data and models permit, EPA must strive to use probabilistic exposure analyses.[77]

iii. Risk Characterization

To ensure that risk characterization is robust and consistent with not only EPA's 2000 Risk Characterization Handbook[78] and EPA Information Quality Guidelines, we recommend that EPA include the following description in the regulatory text, which is consistent with those documents:

> In the risk characterization, particularly when there are findings that a chemical presents an unreasonable risk, for each condition of use evaluated, EPA will present (i) each population addressed by any estimate of applicable human health risk or each risk assessment endpoint, including populations if applicable, addressed by any estimate of applicable ecological risk; (ii) the expected risk or central estimate of risk of the human health risk for the spe cific populations affected or the ecological assessment endpoints, including populations if applicable; (iii) each appropriate upper -bound or lower -bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of ris k and the studies that would assist in resolving the uncertainty; and (v) peer - reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data.

[75] Id. at 7571.
[76] See https://www.epa.gov/tsca-screening-tools/non-cancer-screening-approaches-health-effects.
[77] This recommendation is consistent with the comments from the CSAC on the 1-bromopropane review, see Chemical Safety Advisory Committee Minutes No. 2016-02, at 13.
[78] See EPA Risk Characterization Handbook, available at https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

In addition, the risk characterization summary should be consistent with the Section 26 science standards. As such, EPA should also include the following language at §702.41 in the regulatory text:

> This summary will include, as appropriate, a discussion of (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the inform ation; (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

EPA notes, in particular, that the Agency may exercise its discretion to include discussion of any alternative interpretation of results.[79] This statement should be clarified. To resolve differences of scientific opinion, when reasonable judgments may lead to different interpretations or alternative methods (e.g., linear and non-linear cancer modeling), the Agency should always err on the side of presenting all scientifically valid approaches. Presentation of alternatives should be the norm, not the exception.

For environmental evaluations, EPA notes that the Agency may consider "effects at the individual, species and community level..."[80] Environmental assessments are typically focused on protecting populations, not necessarily individual environmental organisms.[81] EPA must clearly justify any environmental assessments that are conducted at the individual level.

Finally, risk characterization should strive to present what is commonly termed a "reality check." EPA should ensure that its final estimate of risk is reasonable and is scientifically sound considering what is widely known about the chemical and its condition(s) of use. A good example of this can be found in a few earlier assessments that EPA conducted.[82]

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[79] See 82 Fed. Reg. at 7571.
[80] Id.
[81] See EPA's Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, 1997, available at https://semspub.epa.gov/work/HQ/157941.pdf.
[82] See for example EPA's 1985 Mutagenicity and Carcinogenicity Assessment of 1,3-Butadiene, at 6-70 and 6-71 available at https://nepis.epa.gov/Exe/ZyNET.exe/30001EUB.txt?ZyActionD=ZyDocument&Client=EPA&Index=1981%20Thru%201985&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&UseQField=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File

C. Publicly Available Information

Consistent with Section 26(j) of the LCSA, EPA commits to making information available to the public. ACC concurs with this approach and has a few suggested additions for what should be made available.

Consistent with our comments on peer review, EPA should ensure that there is an opportunity for the public to provide comments to peer review panels on key areas of the assessments that warrant detailed review, and the peer reviewers should subsequently provide responses to substantive scientific public comments that they receive. These public comments and the peer reviewer responses should be included in the final peer review report that is placed in the public docket.

In addition to providing a response to public comments received on the draft risk evaluation, EPA should provide a similar response to public comments received on the draft scope document. Both sets of agency responses should be in the public docket.

To ensure that CBI is appropriately used in the risk evaluation process, EPA should use an appropriate third party to review this information. The report from this review should also be placed in the public docket, safeguarding all CBI. This approach will help to facilitate the agencies use of CBI in the risk evaluation process, as appropriate.

D. Reassessment

EPA states that the Agency may reassess a final unreasonable risk determination at any time.[83] EPA should clarify that EPA may reassess a finding of "no unreasonable risk" or a finding of "unreasonable risk" based on a review of available information. There is no justification for reassessment to apply only to findings of "no unreasonable risk." The requirements for reassessment must be applied equally to both positive and negative risk findings. EPA should put in place a transparent petition process that will allow the public to comment on chemicals and conditions of use that may require reassessment. In addition, ACC recommends that when a determination is made to reassess a chemical substance, the Agency begin with prioritization before proceeding to risk evaluation.

E. Third Party Assessments

While EPA has not yet released guidance to assist persons interested in developing and submitting draft risk evaluations which shall be considered by the Administrator, EPA should expect to receive some risk evaluations from third parties for consideration in the process. The

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[83] See 82 Fed. Reg. at 7580.

final rulemaking should describe the process the Agency will use for internally reviewing these risk evaluations and for moving them to peer review expeditiously.

When submitted evaluations follow the same policies and procedures that will be described in the final risk evaluation rule, EPA should commit to reviewing draft risk evaluations within 90 days. This timeframe is consistent with the period of time ACC proposes that EPA allow for public comment on risk evaluations developed by the Agency. ACC also recommends that public comment be simultaneous with internal EPA review. Once the review process is complete, these assessments should move to peer review.

VII. Additional Definitions

The proposed rule discusses other important definitions. Some are new, while others are redefinitions of existing terms. Below ACC provides recommendations to inform EPA's use and interpretation of a few of these definitions.

A. Aggregate Exposure

While EPA provides an appropriate definition of aggregate exposure, consistent with the definition in the EPA Exposure Factors Handbook, ACC is concerned that when considering aggregate exposures, EPA may go beyond the intended scope of what should be in a risk evaluation under the LCSA. Risk evaluations conducted under the LCSA should be consistent with the scope of the LCSA. For instance, the LCSA does not cover the evaluation of pesticides, foods, food additives, drugs, cosmetics, tobacco products, etc. As such, it would be inappropriate for consideration of aggregate exposure to lead to a risk evaluation of non-LCSA products. If EPA felt it necessary to consider such products, any assessment conducted should be done only on a case specific basis and in consultation with the appropriate Agency or program with the statutory authority for the review and assessment of that product. EPA should commit to including relevant authorities and experts when there are such cases. We expect the need to conduct these consultations to be the exception rather than the norm.

B. Categories of Chemical Substances

The term "category of chemical substances" is clearly defined in Section 26(c) of the LCSA. In the proposed rule, EPA specifically notes that, where appropriate, a risk evaluation may be conducted on a category of chemical substances. ACC supports this approach.

EPA explicitly seeks comment on areas where additional transparency, public accountability, and opportunities for public comment can be improved.[84] To be consistent with cross-cutting requirements in Section 26(h), and to be consistent with EPA's general commitment to transparency and public accountability, when EPA finds that it is appropriate to consider a category of chemical substances, this finding should be clearly explained. The justification should include all the factors and considerations which led to the determination that a category approach was appropriate. When such an approach is taken, before EPA begins their risk evaluation, EPA should solicit public comment on its determination that it is appropriate.

[84] See 82 Fed. Reg. at 7565.

C. Potentially Exposed and Susceptible Populations

This term is clearly described in the statute. There is no need for EPA to reinterpret it or broaden the definition. The edits below bring the proposed definition in the regulatory text in line with the statutory definition:

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Agency who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, ~~including but not limited to,~~ such as infants, children, pregnant women, workers, or the elderly. ~~EPA may identify a susceptible subpopulation in an individual risk evaluation upon consideration of various intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits) or acquired (e.g., pre-existing disease, geography, workplace) characteristics that may affect exposure or modify the risk of illness or disease.~~

EPA has suggested modifying the statutory definition for two stated reasons: to clarify that EPA may identify additional populations where warranted, and to include specific authorization for EPA to consider broader factors (e.g., consideration of various intrinsic or acquired factors) when identifying this population.[85] The term "such as" is sufficiently clear to allow EPA to identify additional subpopulations when needed. Had Congress intended to explicitly include other subpopulations, Congress would have chosen different language. Similarly, if Congress felt the need to explicitly define what factors EPA must consider (e.g., intrinsic and extrinsic factors), these factors would have been included in the definition. This is not an area in need of clarification in the regulatory definition.

Similarly, EPA broadens the definition to include explicit consideration of those with illness or disease. While such considerations may very well be appropriate in case-by-case situations for particular conditions of use, had Congress intended this consideration for each condition of use evaluated under the LCSA, the language would have been included in the statute. EPA's proposed revision is clearly intended to broaden the scope of EPA's evaluation. Congress did not support such a broad scope, nor does ACC. We recommend that EPA finalize the definition provided in the statute.

D. Sentinel Exposure

EPA provides a definition for sentinel exposure and notes that while it is not a novel way of characterizing exposure, it is a new term for EPA.[86] EPA does not identify the source for its definition.

ACC is concerned that EPA's proposed definition does not reflect a fundamental understanding of how the concept of sentinel exposure has been used by other national authorities, such as Health Canada or the European Union (EU). In fact the term and use of sentinel exposures is not new in either jurisdiction; as such, it is not new to U.S. chemical manufacturers. The concept of

[85] Id. at 7576.
[86] Id. at 7658.

"sentinel exposure" or "sentinel product" is common in the EU. As was stated in a 2007 publication:

> [A]n interesting, valuable concept is that of the so-called "sentinels of exposure" or "sentinel products". The concept involves identification of a specific product (sentinel product) within a broad category (e.g. liquid laundry detergents within the broad category of household cleaning products) whose usage leads to the highest level of exposure relative to all other products within the category. Therefore, establishing that exposure to the sentinel product is "safe" (lower than an appropriate reference, e.g. a DNEL) allows to conclude that exposure derived from any other product within the category is also safe. This concept is proposed by the Canadian Health Authorities in their 2005 document entitled: "A proposed integrated framework for the health-related components of categorisation of the Domestic Substances List under CEPA 1999" (Health Canada, 2005). The same concept is also described and proposed by the US Soap and Detergent Association (SDA) as one useful approach for what they call "screening-level assessments" (SDA, 2005). This concept can be also applied to specific types of activities within one single type of product to determine the one that is associated with the highest exposure (e.g. laundry pre-treatment of clothing could be the "sentinel activity" among the different potential activities associated with a laundry detergent, such as hand wash, fabric wear, and so on). A similar approach has also been described for cosmetic and personal-care products by the European Cosmetic and Toiletry Association (COLIPA), in collaboration with US Research Institute for Fragrance Materials (RIFM) and the Brussels-based International Fragrance Association (IFRA). In this case, the dermal route is identified as largely predominant and a small number of product types are shown to contribute disproportionately to the exposure. Accounting for the exposure contributed by those key products is all that is really needed for a sound risk assessment.[87]

The definition above is consistent with the approach used by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) in its Targeted Risk Assessment User Guide,[88] which has been used extensively in REACH and is accepted by ECHA, and is also consistent with the approach used by Health Canada.[89] In the approach developed by Health Canada, a quantitative upper bound exposure estimate is used. However, in none of the descriptions provided, does the sentinel exposure equate with the "maximal" exposure to an individual or population. It is a term used to describe the type of product for which exposures will be highest compared to other products or exposures within the similar category. It does not imply that the maximal exposure (which could be the 99.99th percentile or higher) is used for risk evaluation. Thus, EPA's definition is not consistent with the common use of "sentinel exposure." EPA should consult with its Canadian and European chemical regulatory counterparts to improve the definition and approach EPA is intending to use.

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[87] See Van Engelen JG, Heinemeyer G, Rodriguez C. 2007. Consumer exposure scenarios: development, challenges and possible solutions, J Expo Sci Environ Epidemiol. Suppl 1:S26-33, available at http://www.nature.com/jes/journal/v17/n1s/full/7500577a.html.

[88] See ECOTOC User Guide, available at: http://www.ecetoc.org/wp-content/uploads/2014/06/Ecetoc_Tra_Standalone_Consumer_Tool_User_Guide_Jun2014.pdf.

[89] Health Canada developed the ComET^{tm} tool which is described at http://www.tera.org/Peer/Exposure/ExposureMeetingMaterials.htm.

Perhaps for simplification purposes, EPA has provided a succinct definition. However, as noted above, this definition does not appropriately capture how the sentinel exposure approach is currently used. Relying on the highest exposure scenario does not mean that the "maximal" exposure is used. Reasonable values from that highest exposure scenario should be used instead. A risk evaluation should not use a "maximal" exposure value as these values are typically unstable. More appropriate language would include the term "plausible exposure" or "plausible upper bound exposure." In the environmental toxicology field, it is common to use the 95th percentile under average exposure conditions. The "plausible maximum exposure" is not used. Significant revisions are needed to EPA's definition to capture the appropriate use of the sentinel exposure concept.

E. Uncertainty

EPA provides a definition for uncertainty and cites EPA's 2014 Human Health Risk Assessment Framework as the source.[90] However, as written, the definition EPA provides is actually not consistent with the source. EPA's definition should conforms to the edits below to ensure the definition is fully consistent.

> *Uncertainty* means the imperfect knowledge or lack of precise knowledge of the real world, either for specific values of interest or in the description of ~~a~~ the system.

VIII. The Process for Manufacturer Requested Evaluations

A. EPA-Initiated and Manufacturer-Requested Evaluations Should Follow the Same Review Process.

LCSA allows chemical manufacturers to request EPA to conduct a risk evaluation at Section 6(b)(4)(C)(ii). By law, a manufacturer may only request a risk evaluation of a chemical it manufacturers (not of a competitor). By rule, EPA is to specify the "form and manner" for manufacturer requests, as well as to prescribe the criteria for the risk evaluation.

In our view, EPA should largely follow the same process – and apply the same criteria – to manufacturer requested risk evaluations as it does to EPA-initiated risk evaluations arising out of the prioritization process. There is one notable difference: EPA has authority under LCSA to flexibly scope risk evaluations for chemicals with high priority designations to focus on conditions of use that are most relevant and meaningful to risk, and it should do so on a case-by-case basis. The result of this process might be that some risk evaluations cover all conditions of use; others a few; others only one.

In the case of manufacturer-requested risk evaluations, a manufacturer may support only certain conditions of use – in other words, it may sell the chemical only for use in certain kinds of products or processes. A manufacturer may strongly support risk evaluation of its chemical under the conditions of use it supports, but may not be willing to fund evaluation of its chemical for uses supported by its competitors. While we believe EPA can expand the scope of a risk evaluation beyond that requested by a manufacturer, the agency should not impose fees on a

[90] See 82 Fed. Reg. at 7568.

company that requests a risk evaluation in a manner that enriches its competitors. (Similarly, if only one manufacturer requests a risk evaluation on a chemical in a particular condition of use, it would not be appropriate to impose costs on manufacturers that did not request the risk evaluation). It will be important for EPA to address fees equitably in the upcoming fees rule; if not, the agency will discourage manufacturer requests.

This is an important observation, because Congress contemplated that EPA would receive manufacturer requests for risk evaluation, and mandates that a certain number of them be accepted. At full implementation, the law anticipates that EPA will be undertaking 5-10 manufacturer-requested evaluations (assuming that not more than 20 EPA-initiated evaluations are underway). EPA should therefore promulgate criteria that make it sufficiently attractive and possible for manufacturers to avail themselves of the option. EPA should not promulgate criteria that make it largely unworkable and impossible to seek and obtain manufacturer-requested evaluations. EPA's insistence that manufacturer-requested evaluations must include "all" conditions of use obviates the use and utility of the law's provision that allows – and requires EPA to accept manufacturer-requested evaluations in the first place, leads to an absurd result, and undermines the function and purposes of the statute.

B. EPA Should Respond Within Six Months from the End of the Comment Period to the Time it Notifies a Manufacturer of Acceptance of a Request.

EPA should align the six months established for scoping EPA-initiated risk evaluations with those requested by manufacturers. EPA should not require more than 6 months to decide whether to accept or deny a request from a manufacturer for review.

C. EPA Should Not Award "Preference" to Any Manufacturer-Requested Risk Evaluations Until the Statutory Cap is Met.

EPA is required by statute to give preference to manufacturer-requested evaluations for which EPA determines that restrictions by one or more states have the potential to have a significant impact on interstate commerce or health or the environment.[91] There is no other statutory basis for differentiating between requests. EPA proposes to treat this as a required "initial prioritization," after which it will further prioritize chemical substances for risk evaluation "based on initial estimates of exposure(s) and/or hazard(s) under one or more conditions of use or any other factor that EPA determines may be relevant."[92] ACC believes this suggested approach, which could result in manufacturer requests being inappropriately rejected by EPA, is inconsistent with legislative intent, and the efficient flow of risk evaluations under LCSA. We believe that until EPA's cap on manufacturer-requested risk evaluations is met, and except for mandatory preference under TSCA 6(b)(4)(E)(iii), the Agency should accept requests for manufacturer-requested risk evaluations on a first-come, first-served basis. EPA arguably cannot, and should not, deny any otherwise compliant request until 5 evaluations are underway, since there may not be a rational basis to be able to compare requests for evaluation. After EPA has 5 manufacturer-requested evaluations underway, it should apply the same prioritization criteria set out in the prioritization rule for selection of chemicals for evaluation. It should not

[91] TSCA 6(b)(4)(E)(iii).
[92] 82 Fed. Reg. 7569.

impose new criteria of "high hazard" and "high exposure" divorced from the criteria established in the prioritization rule.

We also strongly urge EPA to delete the catch-all provision, "any other factor EPA determines may be relevant." For the manufacturer-requested risk evaluation process to function, manufacturers must have fair notice of the criteria they must meet to have a request considered. An open-ended catchall provision not only undermines congressional intent; it eliminates fair notice to manufacturers of what information they need to gather and prepare in order to have a request considered. This is particularly the case given that manufacturers may need to conduct testing and incur significant costs before they request a risk evaluation.

D. EPA Should Not Require Submission of "All" Prior Risk Assessments by Manufacturers as a Precondition to Accepting a Manufacturer Request.

Section 702.37(b)(4) proposes that manufacturer requests must include a commitment to provide to EPA any referenced information on request, an appropriate request (subject to CBI protection, if applicable). This section provides further, however, that a manufacturer must submit any previous risk assessment conducted by a manufacturer as well as any it "possesses" or "can reasonably obtain." While we appreciate that TSCA § 26(k) requires EPA to take into consideration reasonably available information as part of Section 6 risk evaluations, this should not devolve into a blanket request for certain proprietary reviews undertaken by manufacturers. Many risk assessments fall into that category.

EPA may properly request manufacturers to produce information with a manufacturer request for a risk evaluation where the Agency has legal authority to make the request and the information is otherwise relevant to the risk evaluation, meets data quality standards, and meets Section 26 scientific standards. EPA cannot, however, create new legal authority for itself to demand otherwise protected information as a condition of considering a manufacturer request for risk evaluation.

This is to be contrasted with health and safety results, which may be inputs in a risk assessment but are distinct from a risk assessment. ACC, in fact, has long had a policy in its Chemical Products and Technology Division to make publicly available the final reports or validated final results of environmental, health, and safety research managed or sponsored under the group (subject to exceptions needed to preserve legal rights, such as proprietary rights, data compensation rights or to protect confidential business information).

EPA also may appropriately request a manufacturer to provide, as part of its request, any information that EPA could otherwise require under TSCA Sections 8(a), 8(c), 8(d) (health and safety studies), and 8(e) (which would already have been reported to the agency).

We urge EPA to revise the proposal accordingly to clarify that manufacturers will be expected to produce information relevant to the risk evaluation, and that EPA confirm it will protect CBI and respect other legal doctrines protecting against disclosure.

E. EPA Should Limit Public Comments Accepted on a Manufacturer Request to the Expected Scope of the Risk Evaluation.

As EPA properly notes in the preamble, the agency must grant any manufacturer request that complies with EPA's criteria, until the statutory minimum of 25 percent has been met. EPA may set criteria by rule. Section 702.37(e)(2) proposes a public comment period on valid manufacturer requests for risk evaluations which injects inappropriate criteria – the public is invited to submit comments and information "relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment."

For EPA-initiated risk evaluations, the legal standard that begins the risk evaluation process is EPA's determination that a chemical "may present" an unreasonable risk of injury. A determination that a chemical "presents" an unreasonable risk is not made, if at all, until the end of the risk evaluation process. A determination that a chemical "presents" unreasonable risk triggers risk management action by EPA.

EPA's proposal to accept public comment on whether the chemical "presents an unreasonable risk of injury" is thus inappropriate for three reasons. First, it applies a standard that should not apply at all to manufacturer-requested risk evaluations. These requests bypass the prioritization process, and are not subject to the same requirement that EPA make a high-priority designation based on a particular risk finding. Instead, Congress intended a separate path for manufacturer-requested evaluations, and the only statutory criteria is that EPA must give preference to chemicals where restrictions by one or more states could have a "significant impact" on interstate commerce or health or the environment. EPA's proposed regulations must respect this statutory mandate for prioritizing manufacturer requests.

Second, under no circumstances should EPA apply the legal standard for risk management to its decision whether to accept a chemical for risk evaluation. The "presents" standard is thus inappropriate.

Third, determinations whether a chemical "may present" or "presents" unreasonable risk belong to EPA alone, by statute. The public should not be invited to opine on whether this legal standard has been met.

EPA should revise this proposal. EPA should treat a valid manufacturer request for a risk evaluation as equivalent to a draft scope, and publish the document and accept public comment accordingly.

F. EPA Should Remove the Certification Requirement for Manufacturer-Requested Risk Evaluations.

Section 702.37(b)(5) requires manufacturers to include a signed certification that the information contained in the manufacturer request is "complete" and "accurate." This requirement is impossible to meet; manufacturers cannot simultaneously be asked to provide all reasonably available information, regardless of accuracy, and then be asked to certify its accuracy. Manufacturers cannot reasonably certify the accuracy of information produced by third parties,

or even EPA itself; they can only be asked to certify the accuracy of their own corporate information they collect and manage. They cannot reasonably be asked to provide a citation list and certify the accuracy of the internal information within every citation.

Likewise, manufacturers cannot be reasonably requested to certify the "completeness" of studies or other information, or even internet searches. The very fact that EPA proposes to publish manufacturer requests and seek public comment supports this point – if manufacturers were themselves capable of locating and producing third party information, there would be no need or value for public comment.

IX. Information Collection Request (ICR) Burden Estimates

Associated with the proposed rule, EPA is taking comment on ICR No. 2559.01. ACC is concerned that the burden estimates provided by EPA are far too low. For each manufacture request, EPA estimates that the burden on the public will be 96 hours and $6,935. EPA assumes the hourly wage of the person submitting the request will be $72.22. The information that EPA expects industry to provide in a manufacturer request is similar to compiling all the information that EPA will provide in prioritization and scoping. As scoping will take approximately six months, acknowledging that EPA intends to collect all the data during prioritization, it is fair to assume that it will take at least as long for manufacturers to collect, assemble, review and ensure the integrity of all the hazard and exposure information for all the conditions of use that are relevant. Consistent with EPA's approach,[93] compiling all this information will require staff with expertise in human health, ecotoxicology, fate, engineering and exposure assessment. EPA assumes, for its own staff, conducting a full risk evaluation will take 5,920 hours per chemical. If we divide this over 3 years, that is approximately 1973 hours/year. If we assume scoping takes six months, that equates to approximately 987 hours excluding any contractor resources which EPA will likely also use ($75,000/chemical). Based on this calculation, ACC cannot understand why EPA thinks the collection, assembling, review, integrity assurance, and reporting will take a manufacturer only 96 hours. This assumption appears extremely low, in fact perhaps 10 fold too low.

In addition, as manufacturers will be certifying their submissions, to ensure accuracy and completion, any submission to EPA will need to be reviewed at the highest levels of an organization. EPA assumes that this work will be done at the equivalent of a GS-13 step 5, or $72.22/hour.[94] Looking at the most recent Office of Personnel Management website, for the Washington DC area, a GS-13, step 5, in 2017 will earn an annual salary of $107,435.[95] Considering the importance of this information, as well as the review required to inform the certification, it is likely that senior employees of manufacturers will complete this task. Using the Ninth Triennial Toxicology Survey as our source,[96] it appears that in the chemical industry,

[93] See EPA ICR Attachment 1 in the rulemaking docket.
[94] ACC notes that this value seems incorrect as the most recent OPM tables show a Washington DC employee at the GS-14 step 5 level making an hourly rate of $51.48. See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB_h.pdf.
[95] See OPM salary tables, available at: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB.pdf.
[96] See Ninth Triennial Toxicology Salary Survey, Table 25, available at https://www.toxicology.org/careers/docs/Gad%20salary%20survey%202016%20IJT.pdf, see table 25.

those with experience above 9 years (thus likely more senior) make a salary ranging from $141,000-177,000, with over 50% of the respondents in this bracket making more than $165,000. Not only is EPA's estimate of the hours needed to develop a manufacturer request too low, but the wage rate is also far too low based on the most recently available published survey results. ACC would be happy to engage further with EPA to assist the Agency in making much needed refinements to both the hours needed and wage estimates assumed in the ICR.